EXHIBIT 1

March 9, 1954 B. F. PEASE, JR 2,671,444

NONMETALLIC MESH SURGICAL INSERT FOR HERNIA REPAIR

Filed Dec. 8, 1951

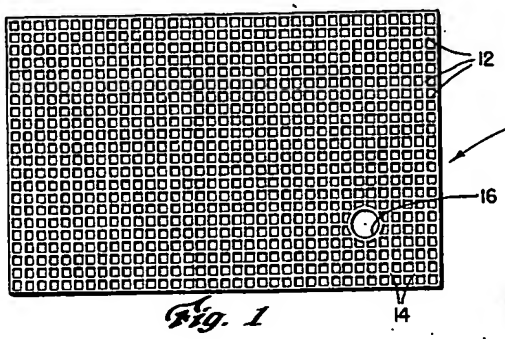

Fig. 1

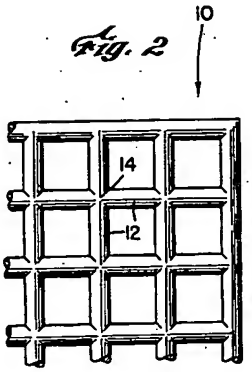

Fig. 2

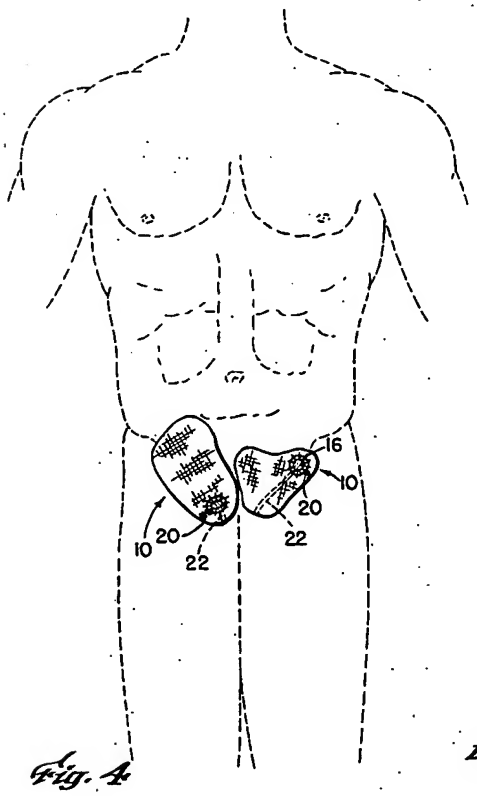

Fig. 4

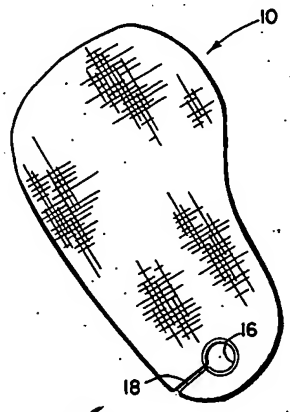

Fig. 3

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Patented Mar. 9, 1954

2,671,444

UNITED STATES PATENT OFFICE

2,671,444

NONMETALLIC MESH SURGICAL INSERT FOR HERNIA REPAIR

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Application December 8, 1951, Serial No. 260,737

3 Claims. (Cl. 128—82)

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My invention relates to surgical inserts adapted to be placed permanently in the human body for the purpose of strengthening weak spots and promoting the growth of new tissues. More particularly it is concerned with a novel insert particularly adapted for use in hernia operations.

Hernias constitute one of the most prevalent disabilities or weaknesses of the human race. Roughly they may be divided into two classifications: (1) hernias of the abdominal region at some structurally weak point, and (2) hernias of any part of the body caused by an injury or as the result of a surgical operation.

Perhaps the most common hernias are those of men located at the openings in the abdominal walls through which pass the spermatic cords. As is well known, hernias of this type can be treated either by mechanical supports, as with trusses or belts, or by surgical repair. With older patients and large hernias surgical repair is less likely to be successful. This is generally supposed to be true because the success of this type of surgery depends greatly upon the physical fitness of the patient and the ability of his body to rebuild completely and quickly the tissues at the point of surgery. In older men the growth of such strengthening tissue is slow and the likelihood of success in hernia operations on such people is correspondingly lessened. On the other hand, the incidence of large, direct or recurrent hernias in this age group is considerably higher than in younger men.

It has been suggested that the percentage of successful hernia repairs by surgery could be greatly increased and the probability of recurrences reduced to an absolute minimum if some strengthening agent or structure could be actually inserted in the body at the time of the operation to "hold" the hernia and promote the growth of strong fibrous tissues. But, so far as I am aware, no satisfactory structure has ever heretofore been created to fill this long felt need. This may be due to the very exacting requirements which must be fulfilled by any such surgical insert.

In the first place, the material of which the insert is composed must be completely compatible with living tissue and body fluids so as to eliminate any likelihood of toxic or allergic reactions on the patient. Secondly, and closely related to the first, the material of which the insert is composed must not react or alter its characteristics, even after years in intimate contact with body tissue and fluids. Thirdly, the

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insert must be sufficiently porous to prevent the formation of fluid pockets against its surface, while during the healing to permit growth through itself of the fibrous tissues to form a strong solid mass. Fourth, the material should not be adversely affected or become brittle by repeated flexing or working due to movement of the patient in his everyday activities. Fifth, it is highly desirable that any such insert be completely permeable to X-rays or other radiation. Sixth, the insert should be capable of being readily trimmed to the desired size and contour by the surgeon in the operating room without causing unravelling of the material so as to yield a strong edge no matter where cut to permit firm suturing in place without danger of the threads pulling loose. Lastly, the insert must be able to provide suitable support and protection close to the spermatic cord, or other cord of the body, which passes through it without likelihood of causing additional irritation or injury, it being noted that usually there is post-operative swelling of the cord.

While such a metal as tantalum possesses a few of these characteristics, I have found that certain resinous materials are far superior thereto and may be formed, according to the invention, into a suitable insert having all of the requisite characteristics aforesaid.

The insert, according to the invention, comprises a sheet of a relatively fine, uniform, open mesh-work of a durable, permanently pliable, non-toxic radiation permeable resinous material which is compatible with body tissues and fluids and inert chemically with respect thereto. All the joints of the mesh-work are preferably unitary, in consequence of which the surgeon may trim the sheet to any desired size and shape without danger of unravelling or the like, the cut edge providing an adequately strong portion for suturing. Preferably near one corner of the sheet there is formed a generally circular opening having a continuous smooth beaded edge to permit the non-irritating passage therethrough of the spermatic or other cord. Optionally, in the use of the insert, the surgeon may cut a slot from one edge of the sheet into the opening to permit insertion of the cord and, thereafter, either suture the edges of the slot together or, alternatively, he may widen the slot to form a U-shaped opening from the edge of the sheet with the aforesaid original opening constituting the base of the U. Because of the availability of a mesh-work in all parts of the insert, the surgeon may suture the same to the body tissues

at any convenient location. The mesh-work itself promotes the ready growth therethrough of repair tissue and the insert is adapted to remain permanently in the body, facilitating the body's own efforts to repair the hernia and minimizing the chance of recurrence without danger of future difficulties because of irritation, corrosion or the like.

In the drawings, I have illustrated one preferred embodiment of the invention, like numerals referring to like parts in the several views, and in which:

Fig. 1 is a plan view of a surgical insert blank sheet according to the invention;

Fig. 2 is a fragmentary enlarged plan view of a portion of the mesh-work of the insert as shown in Fig. 1;

Fig. 3 is a plan view of the insert of Fig. 1 after being trimmed to desired size and shape by the surgeon and having a slot cut from its edge into the internal opening; and

Fig. 4 is a schematic illustration showing the application of two inserts, according to the invention, in the repair of a double hernia.

The insert, indicated generally by the numeral 10, comprises a mesh-work of interconnecting meshes 12. As best seen in Fig. 2, the meshes are integral at their joints 14 so that when the sheet is trimmed to the contour illustrated in Fig. 3 there will be no unravelling no matter where it is cut. I have found that the sheet 10 may conveniently be molded as an integral piece by the use of heat and pressure from a suitable polyethylene resin such as that currently sold by Du Pont and known by the trade-mark "Alathon." This material has been found to be compatible with body tissues and fluids and will not cause toxic or allergic reactions and is chemically inert with respect thereto so that it can remain for many years planted within the human body.

Likewise, I have found that this resinous material possesses the additional requisite qualities of being permanently pliable, so that it remains unaffected by repeated flexings, and is permeable to X-rays and other penetrative radiations, nevertheless having the requisite strength for the use contemplated by the present invention.

It is evident that other existing materials may be found suitable for use in the manufacture of the insert of the invention and that still others may be discovered by those working in this art and, consequently, it will be understood that the invention is independent of any particular material herein described.

Inwardly from the edges of the sheet 10 at some convenient location, usually near a corner, is formed an opening 16 with a strong, smooth beaded edge which is adapted, when the sheet has been trimmed and inserted, non-irritatingly to receive the spermatic cord. As shown in Fig. 3, in order to permit entrance of such cord, the surgeon may cut a slit 18 from the outer edge of the sheet into the opening 16. After insertion this slit 18 may be sutured by the stitches 20, as seen in Fig. 4. As will further be seen in Fig. 4, the spermatic cords 22 pass through the openings 16, and the edges of the latter may optionally be sutured to the body tissue.

If desired the slit 18 may optionally be widened by the surgeon to form a U-shaped opening, the base of which is formed by the smooth curved edge of the opening 16. In such case the widened slit 18 remains permanently open but the edges thereof may be sutured to the body tissue.

While I have herein described and disclosed a preferred embodiment of the invention, it will nevertheless be understood that the same is capable of modifications and changes within the spirit and scope of the appended claims.

I claim:

1. A surgical insert for use in hernia repair or similar surgical operations and adapted, in use, to be trimmed to size and desired contour by the surgeon, prior to permanent implantation in the human body, which comprises a sheet of relatively fine mesh-work of a permanently pliable, non-toxic, non-metallic material which is inert chemically with respect to body tissues and fluids, the meshes thereof being integral at their joints to permit non-ravelling trimming by the surgeon, said sheet having an opening with a strong, smooth, beaded edge, said sheet being adapted, in the use thereof, after trimming, to be slit from its outer edge to the edge of said opening to permit entry of a cord of the body into said opening, the latter being adapted non-irritatingly to receive and permanently to retain said cord and said mesh-work being adapted to promote the growth of strengthening body tissue therethrough.

2. An article in accordance with claim 1 in which said material is a resinous material.

3. An article in accordance with claim 1 in which said material comprises polyethylene resin.

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